

NIH-DCI Phase III | DC-STEP

Report of Adverse Event Form

Place ID Label Here

A. Identification of Adverse Event:

1. Date of adverse event: | | | - | | | - | | | | |
2. Date event learned of: | | | - | | | - | | | | |
3. Person reporting event: _____
4. Signature of Supervisor/PI: _____
5. Date signed: | | | - | | | - | | | | |

B. Description of Adverse Event

NRT

1. Description of event: (MARK ALL THAT APPLY)

- a ☐ Preterm birth
 - b ☐ LBW birth
 - c ☐ Still birth
 - d ☐ SGA
 - e ☐ Miscarriage
 - f ☐ Recruitment of underage participants <18
- Significant symptoms related to the Patches leading to discontinuation of the patches:
- g ☐ Tachycardia
 - h ☐ Change in fetal movement patterns
 - i ☐ Persistent nightmares
 - j ☐ Other → SPECIFY _____

2. Additional details (optional):

3. How was event learned of? (MARK ALL THAT APPLY)

- a ☐ Intervention session → 3b. Specify session #: _____
- c ☐ Baseline evaluation interview
- d ☐ FU evaluation interview → 3e. Specify FU: _____
- f ☐ Other calls (scheduling, etc.)
- g ☐ Other → 3h. SPECIFY _____

C. Actions Taken

1. Actions taken by project staff (with dates)? _____
2. Actions taken by others (with dates)? _____

D. RTI USE ONLY

- 1a. Date Received at RTI: | | | - | | | - | | | | |
- 2a. Date Submitted to GWU: | | | - | | | - | | | | |
- 3a. Date Submitted to NICHD: | | | - | | | - | | | | |
- 4a. Date Added to Adverse Event Database: | | | - | | | - | | | | |
- 2b. Submitted By: _____
- 3b. Submitted By: _____
- 4b. Added By: _____

Comments: _____

ETS

4. Description of event: (MARK ALL THAT APPLY)

- a ☐ Subject under the age of 18 is recruited
- b ☐ Subject suffers injury [injuries of interest that will be reported will be plausibly related to intimate partner violence] leading to ER visit, hospitalization, or death
- c ☐ Subject manifests suicidal ideation
- d ☐ Subject reveals/reports incident of child abuse or neglect
- e ☐ Infant injury requiring ER visit, or hospitalization following delivery [injuries of interest that will be reported will be plausibly related to child abuse/neglect]
- f ☐ Infant death following delivery
- g ☐ Other → SPECIFY _____

5. Additional details (optional):

6. How was event learned of? (MARK ALL THAT APPLY)

- a ☐ Clinic intervention session → 3b. Specify session #: _____
- b ☐ Phone intervention session → 3c. Specify session #: _____
- d ☐ Home visit → 2a. Specify session #: _____
- e ☐ Baseline evaluation interview
- f ☐ FU evaluation interview → 3g. Specify FU: _____
- h ☐ Other calls (scheduling, etc.)
- i ☐ Other → 3j. SPECIFY _____

INSTRUCTIONS

1. The completed *Report of Adverse Event Form* should be e-mailed to Dr. Ayman El-Mohandes (sphaxe@gwumc.edu) or Dr. Susan Blake (sdblake1@aol.com) as appropriate, for approval and signature, copying Prag Katta (pippsk@gwu.edu) and Adam Safir (asafir@rti.org).
2. The signed form should be scanned and e-mailed to Dr. Michele Kiely (kielym@nih.gov) and Adam Safir (asafir@rti.org).
3. The original form should be placed in the subject's file (at the clinic, at CNMC, or at GWU).